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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,844	07/08/2003	Laura C. Blumberg	PC25035A	1729
28523	7590	11/24/2004	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,844

Applicant(s)

BLUMBERG ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3,8,10,14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-9,12 and 13 is/are rejected.
- 7) ☐ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 2, 7-9, 11 and claims 1, 4-6, 12-13 reading on the elected compounds in the reply filed on Sept. 7, 2004 is acknowledged. The traversal is on the ground that the examiner has not shown how a search without restriction would be a burden.. This is not found persuasive because it was clearly delineated in the restriction that how each group of compounds belonged to independent and distinct class/subclass of heterocyclic compounds being recognized in the art as separate core structure. In addition, the broad scope such as group III, can not be classified without a species election. Therefore, although the word "burdensome" was not used, the burden is self evident. In addition, it was evidence by Ca 138:153539 that the W is phenyl core compounds are NMDA receptor antagonists, i.e. no common core for the same utility.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 7-9, 11 and claims 1, 4-6, 12-13 reading on the elected compounds are prosecuted. The remaining compounds of claims 1, 4-6, 12-13 and claims 3, 8, 10,14-15 are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention nor to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

Art Unit: 1625

Nature of invention

The claims are drawn to pharmaceutical composition of the claimed compounds for "treating or preventing a disorder..... that can be treated or prevented by inhibiting MIP-1 α and/or RANTES binding to the receptor CCR1...."

The state of the art and predictability

CCR1 receptor is a cytokine receptor (CA 130:138110). Cytokine receptor function has been known in the art to be highly unpredictable with limited understanding of the mechanisms that lead to one activity over another when a "specific" cytokine is involved in a specific biological reaction (see CA 125:31527). Therefore, such specific nexus can not provide extrapolation to large varieties of therapeutically effects as found in claims 12-13.

The amount of guidance and working examples

In the specification, "no" disclosure on what effect on the receptor binding with any of the disclosed compounds. In view of the high degree of unpredictability and no guidelines as to how to pick and choose compounds for dosage formulation, the "effective" amount of claims 12-13 lacks description and enabling guidelines.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is very confusing as to "what" is the scope of the claims because claim 1 requires that at least one of R²-R⁵ being C₁₋₆alkyl while compounds 1-4, 9-10 of claim 11 are R²-R⁵ are hydrogen compounds.

The claims are given the broadest interpretation to be including all the compounds including that R²-R⁵ are hydrogen compounds in the following rejection.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Art Unit: 1625

Claims 1-2, 4-9, 12-13 are rejected under 35 U.S.C. 102(g) as being anticipated by US 2004/0157886, see claim 1 and 24 supplemented with p.35 example 245.

Please note that the filing date of the US 2004/0157886 is within six month of the filing date of the instant application and the species encompassed by the claims anticipated the instant claims when Z is NR⁸ and R⁸ is H.

5. Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 11 is drawn to Z is "O" compounds which are neither anticipated nor rendered obvious by the art of record.


6.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS
Nov. 18, 2004


Celia Chang
Primary Examiner
Art Unit 1625